Bard Electrophysiology
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JAN 11 2002

BARD

VI. 510(k) SUMMARY: FOR THE SURELINK, TEMPLINK, AND TEMPLINK M EXTENSION CABLES

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990.

A. Submitter's Information

Name:	Bard ***electrophysiology*** Division of C.R. Bard, inc.
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Contact Person:	Deborah L. Herrington Manager, Regulatory Affairs
Date of Preparation:	October 30, 2001

B. Device Name

Trade Name:	SureLink Extension Cable TempLink Extension Cable TempLink M Extension Cable
Common/Usual Name:	Electrode cable (including connector)
Classification Name:	Patient Transducer and Electrode Cable (including connector)

C. Predicate Device Names(s)

SureLink Extension Cable
TempLink Extension Cable
TempLink M Extension Cable

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D. Device Description/Indications for Use

Description

The SureLink, TempLink, and TempLink M Extension Cables are accessories that are used in conjunction with the appropriate diagnostic or ablation catheter. Cables, when initially introduced, provided an alternate means of electrically connecting EP catheters to recorders versus the catheter connecting directly to the recorder. The use of cables allows the catheter to remain in the sterile field, the recorder junction box doesn't have to enter the sterile field, and the cable provides more working length. The cables are offered in several lengths ranging from 7 to 10 feet in length.

Indications

SureLink Extension Cables

The SureLink extension cable is indicated for use during electrophysiology studies in conjunction with the appropriate electrode catheter. This cable may be reused subject to the cleaning and sterilization restrictions herein.

TempLink/TempLink M Extension Cables

The TempLink extension cable when used in conjunction with a thermistor configured Stinger/Stinger S catheter is indicated for use during cardiac ablation with set power to 50W.

The TempLink M extension cable when used in conjunction with a thermocouple configured Stinger M/Stinger SM catheter is indicated for use during cardiac ablation with set power to 50W.

These cables may be reused subject to the cleaning and sterilization restrictions herein.

E. Technological Characteristics/Performance Data Summary

The "510(k) Substantial Equivalence Decision-Making Process (Detailed)" decision tree (CDRH 510(k) Manual 92-4158) was utilized to make a determination of substantial equivalence. This decision tree is depicted in Figure IV-1 with the decision points relevant to the SureLink, TempLink, and TempLink M cables indicated by highlighting. The answers to the following questions at the indicated decision points in Figure IV-1 lead to a determination of substantial equivalence.

New Device is Compared to a Marketed Device?

Yes. The SureLink, TempLink, and TempLink M Extension cables with the reuse claim are compared to their no reuse claim counterparts. The only change to the indications for use statement is the addition of the reuse claim subject to the cleaning and sterilization restrictions provided in the instructions for use.

Does the New Device have the Same Indications Statement?

No. The indication statement for the SureLink cables, subject of this 510(k), and that of the predicate device are similar. Both are indicated for use during electrophysiology studies in conjunction with the appropriate electrode catheter. The SureLink cable, subject of this 510(k), is additionally indicated for reuse subject to the cleaning and sterilization restrictions included in the instructions for use (IFU).

The indication statement for the TempLink cables, subject of this 510(k), and that of the predicate device are similar. When used in conjunction with a thermistor configured Stinger / Stinger S catheter the TempLink cable is indicated for use during cardiac ablation with set power to 50W.

The indication statement for the TempLink M cable, subject of this 510(k), and that of the predicate device are similar. When used in conjunction with a thermocouple configured Stinger M catheter the TempLink M cable is indicated for use during cardiac ablation with set power to 50W.

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The TempLink/TempLink M cables, subject of this 510(k), are additionally indicated for reuse subject to the cleaning and sterilization restrictions included in the IFU.

Do the Differences Alter the Intended Therapeutic/Diagnostic/etc. Effect ?

No. The cables with the reuse claim continue to be used as originally described. These cables, like their respective predicate devices, are not placed intravascularly and have no patient body contact. These cables are accessory devices that continue to be used in conjunction with their respective therapeutic or diagnostic catheters.

New Device Has Same Intended Use and May Be "Substantialy Equivalent"

Does New Device Have the Same Technological Characteristics, e.g., Design, Materials, etc.?

No. The SureLink, TempLink, and TempLink M cables are similar to their predicate devices. The design of each cable remains unchanged. The internal tail component was originally made from tinsel wrapped kevlar, but was replaced with standard copper wire that is easier to work with in manufacturing, more readily available, and found equivalent to the kevlar material. With respect to the reuse claim for EO, steam autoclave, and Sterrad sterilization, data to support this claim is provided in the Appendices.

Could the New Characteristics Affect Safety or Effectiveness?

No. The addition of a reuse claim could effect safety and/or effectiveness for a number of devices. However, these cables are accessories to their respective catheters and are not placed intravascularly, nor do they have patient body contact. Regarding effectiveness, failure of the cable to not perform as intended would result in physician inconvenience and have no negative impact on the patient.

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. Although the design of the cables has not changed, and the materials of construction are similar (change in internal tail component from tinsel wrapped kevlar to copper wire), data are required to support the reuse claim.

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Are Performance Data Available to Assess Equivalence?

Yes. Performance data is provided in the Appendices with respect to the reuse claim.

Performance Data Demonstrate Equivalence?

Yes. The performance data demonstrates that the SureLink, TempLink, and TempLink M cables continue to perform as intended after the specified number of cleanings and resterilizations as described in the instructions for use.

Therefore, the SureLink, TempLink, and TempLink M cables with the reuse claim are "Substantially Equivalent" to their respective predicate devices.

SUBSTANTIALLY EQUIVALENT DETERMINATION:

The determination of substantial equivalence is based on the decision tree found in Figure IV-1, the safety information provided in Section IV.C, the effectiveness results regarding cable performance summarized in Section IV, and the actual data provided in the Appendices. Refer to the table under the tab "Appendices" for the actual information provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2002

Ms. Deborah L. Herrington
Manager, Regulatory Affairs
C.R. Bard, Inc.
Bard Electrophysiology
55 Technology Drive
Lowell, MA 01851

Re: K013598
Trade Name: Reuse Claim for the Bard Electrophysiology SureLink, TempLink, and TempLink M Extension Cables
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable
Regulatory Class: Class II (two)
Product Code: DSA
Dated: October 30, 2001
Received: October 31, 2001

Dear Ms. Herrington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

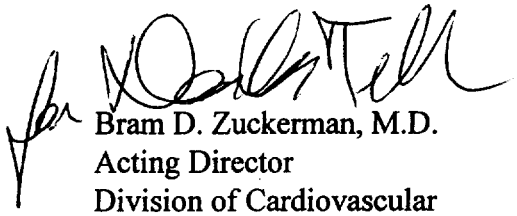
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. INDICATIONS FOR USE

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Device Name: SureLink Extension Cables

Indications for Use:
The SureLink extension cable is indicated for use during electrophysiology studies in conjunction with the appropriate electrode catheter. This cable may be reused subject to the cleaning and sterilization restrictions herein.

Device Name: TempLink/TempLink M Extension Cables

Indications for Use:
The TempLink extension cable when used in conjunction with a thermistor configured Stinger/Stinger S catheter is indicated for use during cardiac ablation with set power to 50W.

The TempLink M extension cable when used in conjunction with a thermocouple configured Stinger M catheter is indicated for use during cardiac ablation with set power to 50W.

These cables may be reused subject to the cleaning and sterilization restrictions herein.

Contraindications:
No known contraindications for the SureLink, TempLink, and TempLink M Extension cables.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013598